

Appl. No. 09/848,948  
Reply to Advisory Action mailed June 6, 2005  
Response dated July 8, 2005

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claim 1 (Currently amended): A method for diagnosis of cancer in a subject comprising:

(a) detecting a S100-A7 protein at least one S100 protein selected from the group consisting of S100-A7 and S100-A8 in a biological fluid sample derived from a subject; and

(b) comparing the level of protein detected in the subject's sample to the level of protein detected in a control sample,

wherein an increase in the level of S100 S100-A7 protein detected in the subject's sample as compared to a control sample is an indicator of a subject with cancer.

Claim 2 (Currently amended): The method of claim 1 wherein the S100 S100-A7 protein is detected using an immunoassay.

Claim 3 (Previously presented): The method of claim 2 wherein the immunoassay is an immunoprecipitation assay.

Claim 4 (Previously presented): The method of claim 1 wherein the sample is a serum

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sample.

Claim 5 (Cancelled)

Claim 6 (Withdrawn): The method of claim 1 wherein the cancer is breast cancer.

Claim 7 (Withdrawn): The method of claim 1 wherein the cancer is colon cancer.

Claim 8 (Withdrawn): A method for diagnosis of a subject with cancer comprising:

- (a) contacting a serum sample derived from a subject with a sample containing S100 protein antigens under conditions such that a specific antigen-antibody binding can occur; and
- (b) detecting immunospecific binding of the autoantibodies to the S100 protein in the subject's serum sample,  
wherein the presence of autoantibodies indicates the presence of cancer.

Claim 9 (Withdrawn): The method of Claim 8 wherein the step of detecting the autoantibodies in the subject's serum sample comprises the use of a signal-generating component bound to an antibody that is specific for antibodies in the subject's serum sample.

Claim 10 (Withdrawn): The method of Claim 9 wherein the presence of autoantibodies in the serum sample is measured by an immunoassay comprising:

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(a) immobilizing one or more S100 protein onto a membrane or substrate;

(b) contacting the membrane or substrate with a subject's serum sample;

and

(c) detecting the presence of autoantibodies specific for the S100 protein  
in the subject's serum sample,

wherein the presence of autoantibodies indicates the presence of cancer.

Claim 11 (Withdrawn): The method of claim 8 wherein the cancer is lung cancer.

Claim 12 (Withdrawn): The method of claim 8 wherein the cancer is breast cancer.

Claim 13 (Withdrawn): The method of claim 8 wherein the cancer is colon cancer.

Claim 14 (Currently amended): A kit for diagnosis of cancer in a subject comprising  
a component for detecting the presence S100 protein in a biological sample, wherein  
said S100 protein is S100-A7 selected from the group consisting of S100-A7 and S100-A8,  
wherein the component for detecting the S100 protein is an anti-S100 antibody,  
such that the presence of S100 protein in the subject's sample as compared to a control  
sample is an indicator of a subject with cancer.

Claim 15 (Cancelled):

Claim 16 (Previously presented): The kit of claim 14 wherein the anti S-100 antibody

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is labeled.

**Claim 17 (Previously presented):** The kit of claim 16 wherein the label is a radioactive, fluorescent, colorimetric or enzymic label.

**Claim 18 (Previously presented):** The kit of claim 14 further comprising a labeled second antibody that immunospecifically binds to the anti-S100 antibody.

**Claim 19 (Withdrawn):** A kit for diagnosis and prognosis of cancer in a subject comprising a component for detecting the presence of S100 autoantibodies in a sample.

**Claim 20 (Withdrawn):** The kit of claim 19 wherein the component is an S100 antigen.

**Claim 21 (Withdrawn):** The kit of claim 20 wherein the S100 antigen is labeled.

**Claim 22 (Withdrawn):** The kit of claim 20 wherein the S100 antigen is linked to a solid phase.

**Claim 23 (Withdrawn):** The kit of claim 19 further comprising a component for detection of the S100 autoantibody.

**Claim 24 (Withdrawn):** A method of immunizing a host against an S100 protein, S100 derived peptide or differentially modified S100 protein, comprising inoculating the

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host with an S100 antigen in a physiologically acceptable carrier, wherein immunization results in a production of antibodies directed against said S100 antigen.

Claim 25 (Withdrawn): The method of claim 24 wherein the host is suffering from a disease characterized by the overproduction of S100 protein.

Claim 26 (Withdrawn): The method of claim 25 wherein the disease is cancer.

Claim 27 (Withdrawn): The method of claim 26 wherein the cancer is lung cancer.

Claim 28 (Withdrawn): The method of claim 26 wherein the cancer is breast cancer.

Claim 29 (Withdrawn): The method of claim 26 wherein the cancer is colon cancer.

Claim 30 (Withdrawn): The method of claim 24 wherein the S100 protein is selected from the group consisting of S100-AG, S100-A7, S100-A8 and S100-A9.

Claim 31 (Withdrawn): A composition for immunizing a host comprising at least one S100 protein and an adjuvant.

Claim 32 (Withdrawn): The composition of claim 31 wherein the S100 protein is selected from the group consisting of S100-AG, S100-A7, S100-A8 and S100-A9.

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Claim 33 (New): A method for diagnosis of breast cancer or colon cancer in a subject comprising:

- (a) detecting at least one S100 protein selected from the group consisting of S100-A7 and S100-A8 in a biological fluid sample derived from a subject; and
- (b) comparing the level of protein detected in the subject's sample to the level of protein detected in a control sample,

wherein an increase in the level of S100 protein detected in the subject's sample as compared to a control sample is an indicator of a subject with breast cancer or colon cancer.

Claim 34 (New): A kit for diagnosis of breast cancer or colon cancer in a subject comprising a component for detecting the presence of a S100 protein in a biological sample, wherein said S100 protein is selected from the group consisting of S100-A7 and S100-A8, wherein the component for detecting the S100 protein is an anti-S100 antibody, such that the presence of S100 protein in the subject's sample as compared to a control sample is an indicator of a subject with breast cancer or colon cancer.